STATEMENT OF H. DANIEL ROTH ON EPA'S HEALTH RISK ASSESSMENT OF THE OZONE DATA

BEFORE THE HOUSE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS AND SUBCOMMITTEE ON HEALTH AND ENVIRONMENT

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I am testifying here today to describe my findings from an assessment of EPA's estimates of the health risks of ozone exposures. The Agency's risk estimates, which are published in the EPA Ozone Staff Paper, are based on exposure models developed by Johnson et al. and risk models developed by Whitfield et al.

In summary, EPA's assessment consists of three parts (Chart 1): (1) evaluating the ozone health effects data; (2) determining the ozone exposure levels of the general public; and (3) integrating the data on health effects with exposures to calculate the risks of ambient ozone levels. There are problems with EPA's analyses in each of these steps which, when corrected for, would show that the Agency in all likelihood inflated the risks of exposures to ambient ozone.

Evaluation of the Health Effects Data: With respect to EPA's analysis of the health effects data (Item 2 in Chart 2), the Agency was very selective and failed to consider several studies that did not show adverse ozone effects. For example, in its evaluation of the human clinical data on greater than six hours of exposure, EPA did not consider five studies that show no ozone effects (Chart 3). Thus, in the Agency's analysis, three out of the three studies considered show ozone effects and in reality only three out of eight studies in this category indicate effects.

In addition, EPA did not take into account the shortcomings in some of the health data it considered (Item 2, Chart 2). Of the nine pulmonary function studies upon which the Agency relies (Chart 4): five fail to adjust for critical factors such as age, weight, height, or smoking status; five studies have problems

such as inadequate sample sizes; and eight studies fail to adjust for variations in pulmonary variations unrelated to pollution (such as diurnal variations).

EPA's failure to acknowledge and incorporate the nonsignificant findings, as well as EPA's failure to recognize the limitations of the studies it did consider calls into question EPA's assumptions about the health effects caused by ozone.

Evaluation of the Ozone Mortality Data: Regarding the ozone mortality data specifically, in recent months several investigators have suggested that effects might exist at current ambient levels. I, however, agree with EPA's conclusion in the Staff Paper:

> *"... although an association between ambient ozone exposures in areas with very high ozone levels and daily mortality has been suggested, the strength of any such association remains unclear at this time."* -- pages 41-2 Staff Paper.

Of the ten ozone mortality studies reviewed in the Criteria Document only one shows a statistically significant ozone effect (Chart 5). However, that single study (Kinney & Ozkaynak, 1991) -- as well as a few additional recent studies that have been cited as showing an association between ambient levels of ozone and mortality -- have serious shortcomings (Chart 6).

For example, Ozkaynak et al. 1995 uses only a single model to analyze the Toronto data, which is a serious shortcoming because it is well known that results from statistical analyses of daily mortality data are extremely dependent upon the model used to analyze the data. Other models should have been used as a means of comparison. Furthermore some studies do not fully adjust for temperature, which is a critical variable in mortality studies. Finally, in many analyses they neglect to consider concentrations of other critical pollutants.

To further assess the association between daily ozone and mortality in Toronto (1981-1992), I have examined these data using Poisson autoregression analyses (Chart 7). Other variables considered in my analyses are day of week, time trends, current and three previous days temperature, barometric pressure, and dewpoint. My results indicate that in none of the years of the study was ozone a positive significant predictor of mortality.

In about half the years it was positively associated (but not significantly) with ozone and in the other years it was negatively associated (but not significantly). Also, this result did not change if the data from all the years of the study are examined collectively (Chart 8). Thus, based on a fairly complete analysis of the Toronto data there is little evidence of an association between mortality and ozone. (I would be happy to provide the subcommittee with more information on these analyses, at their request.)

Evaluation of the Exposure Data: There are also problems with EPA's analysis of the exposure data, including:

- It does not consider annual variations in ozone levels.
- It does not consider seasonal variations.
- It does not appear to be based on a representative sample of the general population.
- It is based on questionable statistical assumptions.
- Population data in the analysis which come from the 1990 U.S. Census is incompatible with housing data which comes from the 1980 U.S. Housing Survey.

Evaluation of the Risk Analysis: Likewise some of the drawbacks with EPA's integration of the health data with the exposure data include:

- It is based on extrapolating health data on males to females and on adults to children.
- It is based on statistically biased estimates of effects.
- It fails to adjust for statistical variations.

- It fails to consider the interaction between ozone and other pollutants.
- It fails to calculate the statistical significance of the health consequences that can be expected at different standard levels.

Conclusion: The failure to recognize the shortcomings of the basic underlying health data has led EPA to inflate the health risks of ozone because the effects observed in many of the studies might be due to factors other than ozone exposures. The failure to consider negative or insignificant ozone health studies also contributes to the inflation of the health risks of ozone. Finally, the problems with EPA's estimate of the population exposures and the health risk assessment might have distorted all of the Agency's findings.

It is not possible, based on these data and analyses, to conclude that there would be different health effects associated with various levels suggested for an 8-hour ozone standard or the existing 1-hour level. In fact, even EPA's existing, but flawed, risk assessment shows no statistically significant differences among the options.

Chart 1

OUTLINE OF EPA MODEL FOR CALCULATING OZONE HEALTH RISKS

HEALTH DATA

EXPOSURE DATA

HEALTH RISKS

Chart 4

SUMMARY OF NINE O_3 HUMAN CLINICAL STUDIES

Study Author	Health Endpoints	STUDY PROBLEMS: Measurement Error	STUDY PROBLEMS: Confounding Factor	STUDY PROBLEMS: Other Problems
Avol 1984	Pulmonary	T	T	
Folinsbee	Pulmonary	T		T
Horstman	Pulmonary	T		T
Kulle	Pulmonary	T		T
McDonnell 1985	Pulmonary	T	T	
McDonnell 1991	Pulmonary		T	T
McDonnell 1993	Pulmonary	T	T	
McKittrick	Pulmonary	T		T
Seal	Pulmonary	T	T	

Chart 5

SUMMARY OF O_3 MORTALITY STUDIES

Calif. Dept. of Health, 1955, 1956, 1957	**Los Angeles**	**NS**
Massey et al., 1961	**Los Angeles**	**NS**
Mill, 1957	**Los Angeles**	**NS**
Hechter & Goldsmith, 1951	**Los Angeles**	**NS**
Biersteker & Evendijk, 1976	**Netherlands**	**NS**
Shumway et al., 1988	**Los Angeles**	**NS**
Kinney & Ozkaynak, 1991	**Los Angeles**	**S**
Schwartz, 1991	**Detroit**	**NS**
Dockery et al., 1992	**St. Louis-Harriman**	**NS**

Chart 6

SUMMARY OF PROBLEMS WITH RECENTLY CONDUCTED O_3 MORTALITY STUDIES

		STUDY PROBLEMS			
Study	Area	Significance of Ozone	Model Selection	Confounding Factor	Other Problems
Ozkaynak et al. 1995	Toronto	Yes	T	T	T
Kinney & Ozkaynak 1991	Los Angeles	Yes	T	T	T
Kinney et al. 1995	Los Angeles	Mixed		T	T
HEI 1997 Samet et al.	Philadelphia	Yes	T	T	
HEI 1996	Mexico	Mixed	T	T	

Loomis et al.

Chart 8

SIGNIFICANCE OF OZONE ON TORONTO MORTALITY

CONSIDERING OTHER POLLUTANTS IN MODEL

POLLUTANTS IN MODEL	OZONE SIGNIFICANCE
Ozone alone	NS
Ozone + TSP	NS
Ozone + SO_2	NS
Ozone + SO_2 + TSP	NS

Chart 2

PROBLEMS WITH HEALTH ANALYSES

- **IT DOES NOT CONSIDER MANY NEGATIVE OZONE STUDIES.**

- **IT FAILS TO ADDRESS THE SHORTCOMINGS IN MANY OF THE CITED STUDIES.**

Chart 7

SIGNIFICANCE OF OZONE ON MORTALITY BY YEAR IN TORONTO

YEAR	OZONE SIGNIFICANCE	YEAR	OZONE SIGNIFICANCE
1981	NS	1987	NS
1982	NS	1988	NS
1983	NS	1989	NS
1984	NS	1990	NS
1985	NS	1991	NS
1986	NS	1992	NS